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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ROONEY et al.  
Title: HIGH PERFORMANCE COIL WIRE

Docket No.: BSP2102US02

Box PATENT APPLICATION  
Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate under 37 CFR § 1.10.
- ☒ Request for Continuation Application Under 37 C.F.R. 1.53(b) with a copy of the prior application as filed in U.S. Serial No. 09/078,946, consisting of: Specification (12 pgs. including 21 claims); Abstract (1 pg.), and 1 formal drawing sheet; declaration as filed in U.S. application Serial No. 09/078,946.
- ☒ **PLEASE CHARGE DEPOSIT ACCOUNT NO. 19-0765 for the required filing fee of \$690.**
- ☒ A preliminary amendment (2 pages).
- ☒ A return postcard.

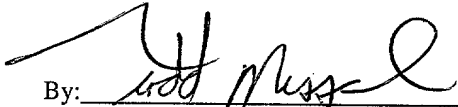
*The Filing Fee has been calculated below as follows (claims as amended in Preliminary Amendment):*

**CLAIMS AS FILED**

	No. Filed		No. Extra	Rate	Fee Total
Total Claims:	6	- 20 =	0	x \$18 =	\$0
Independent Claims:	1	- 3 =	0	x \$78 =	\$0
Basic Fee:					\$690
<b>TOTAL:</b>					\$690

Please charge any additional required fees or credit overpayment to Deposit Account No. 19-0765. A duplicate copy of this sheet is enclosed.

SCIMED Life Systems, Inc.  
One SCIMED Place, Maple Grove, MN 55311-1566  
(612) 494-2880

By:   
Name: Todd P. Messal  
Reg. No.: 42,883

**CERTIFICATE UNDER 37 C.F.R. § 1.10:**

"Express Mail" mailing label number: EL056549561US

Date of Deposit: June 20, 2000

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Brenda House  
Name: Brenda House

jc836 U.S. PTO  
09/597179  
06/20/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: ROONEY et al.

Examiner: Unassigned  
(in Parent App.: 09/078,946)

Serial No. : Unassigned  
(in Parent App.: 09/078,946)

Art Unit: Unassigned  
(in Parent App.: 3736)

Filed: Concurrently herewith  
(in Parent App.: May 14, 1998)

Docket: BSP2102US02

Title: HIGH PERFORMANCE COIL WIRE

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REQUEST FOR CONTINUATION  
APPLICATION UNDER 37 C.F.R. § 1.53(b)

Box PATENT APPLICATION  
Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Washington, D.C. 20231

Dear Sir:

This is a request for filing a continuation application under 37 C.F.R. § 1.53(b) of prior application Serial No. 09/078,946, filed on May 14, 1998, entitled HIGH PERFORMANCE COIL WIRE, with the following inventor(s):

1	<b>Full Name of Inventor</b>	Family Name ROONEY	First Given Name MAURA	Second Given Name
	<b>Residence &amp; Citizenship</b>	City CAMBRIDGE	State or Foreign Country MASSACHUSETTS	Country of Citizenship USA
	<b>Post Office Address</b>	Post Office Address 10 SHEPARD STREET	City CAMBRIDGE	State & Zip Code/Country MASSACHUSETTS 02138/USA

2	<b>Full Name of Inventor</b>	Family Name RICHARD	First Given Name JOSEPH	Second Given Name
	<b>Residence &amp; Citizenship</b>	City BEDFORD	State or Foreign Country MASSACHUSETTS	Country of Citizenship USA
	<b>Post Office Address</b>	Post Office Address 114 PAGE ROAD	City BEDFORD	State & Zip Code/Country MASSACHUSETTS 01730/USA

3	<b>Full Name of Inventor</b>	Family Name KAPRAVY	First Given Name ANDY	Second Given Name
	<b>Residence &amp; Citizenship</b>	City STOUGHTON	State or Foreign Country MASSACHUSETTS	Country of Citizenship USA
	<b>Post Office Address</b>	Post Office Address 28 PROSPECT STREET	City STOUGHTON	State & Zip Code/Country MASSACHUSETTS 02072/USA

4	<b>Full Name of Inventor</b>	Family Name LIU	First Given Name CLIFFORD	Second Given Name M.
	<b>Residence &amp; Citizenship</b>	City RANDOLPH	State or Foreign Country MASSACHUSETTS	Country of Citizenship USA
	<b>Post Office Address</b>	Post Office Address 24 ALWARD DRIVE	City RANDOLPH	State & Zip Code/Country MASSACHUSETTS 02368/USA

5	<b>Full Name of Inventor</b>	Family Name CHU	First Given Name MICHAEL	Second Given Name S.H.
	<b>Residence &amp; Citizenship</b>	City BROOKLINE	State or Foreign Country MASSACHUSETTS	Country of Citizenship USA
	<b>Post Office Address</b>	Post Office Address 121 BROWNE STREET	City BROOKLINE	State & Zip Code/Country MASSACHUSETTS 02146/USA

6	<b>Full Name of Inventor</b>	Family Name MIRARCHI	First Given Name TOM	Second Given Name
	<b>Residence &amp; Citizenship</b>	City SHREWSBURY	State or Foreign Country MASSACHUSETTS	Country of Citizenship USA
	<b>Post Office Address</b>	Post Office Address 18 CONCORD ROAD	City SHREWSBURY	State & Zip Code/Country MASSACHUSETTS 01545/USA

☒ A copy of the prior application as filed is enclosed including a copy of the oath or declaration filed in the parent application.

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

☒ A preliminary amendment is enclosed.

The filing fee is calculated on the basis of the claims existing in the prior application including any amendment referred to herein.

#### CLAIMS AS FILED

	No. Filed		No. Extra	Rate	Fee Total
Total Claims:	6	- 20 =	0	x \$18 =	\$0
Independent Claims:	1	- 3 =	0	x \$78 =	\$0
Basic Fee:					\$690
<b>TOTAL:</b>					\$690

☒ Please charge Deposit Account No. 19-0765 for the filing fee of \$690.

The Commissioner is hereby authorized to charge any additional fees as set forth in 37 C.F.R. § 1.16 to § 1.18 or 37 C.F.R. § 1.15(b)(1) which may be required to Deposit Account No. 19-0765.

☒ Amend the specification by inserting before the first line the sentence, "This is a continuation of application Serial No. 09/078,946, filed May 14, 1998."

☒ The prior application is assigned of record to Scimed Life Systems, Inc. as recorded at Reel 9325, Frame 0499.

☒ The Power of Attorney in the prior application is to:

Luke Dohmen, Reg. No. 36,783

Peter J. Gafner, Reg. No. 36,517

Todd P. Messal, Reg. No. 42,883

☒ Address all future communications to:

Todd P. Messal, at the address listed below.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code and that willful false statements so made may jeopardize the validity of the application or any patent issuing therefrom.

Respectfully submitted,



Todd P. Messal, Reg. No. 42,883  
Scimed Life Systems, Inc.  
One Scimed Place, M.S. A150  
Maple Grove, MN 55311-1566  
Telephone: (612) 494-2880

Date: June , 2000

**CERTIFICATE UNDER 37 C.F.R. § 1.10:**

"Express Mail" mailing label number: EL056549561US

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By: Brenda House  
Name: Brenda House

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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(in Parent App.: 3736)

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Docket: BSP2102US02

Title: HIGH PERFORMANCE COIL WIRE

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**PRELIMINARY AMENDMENT**

BOX PATENT APPLICATION  
Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Washington, D.C. 20231

Dear Sir:

Applicants respectfully request that the following Preliminary Amendment be made of record and considered before the first Office Action on the merits.

**In the Claims**

Please cancel claims 1-21 and add the following new claims

--22. A guide wire comprising:

an elongate core composed of a nickel-titanium alloy and having a length; and

a coil composed of a second material and surrounding a substantial portion of the

length of the core.

23. The guide wire of claim 22 wherein the coil surrounds a portion of the core near a proximal end of the core.

24. The guide wire of claim 23 wherein the coil surrounds the proximal end of the core.

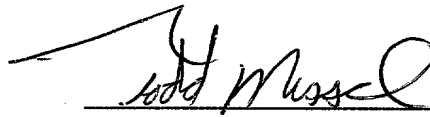
25. The guide wire of claim 22 wherein the coil surrounds the entire length of the core.

26. The guide wire of claim 22 wherein the coil extends along the length of the core from the portion of the core near the proximal end of the core to a portion of the core near a distal end of the core.

27. The guide wire of claim 25 wherein the coil extends along the length of the core from the portion of the core near the proximal end of the core to a portion of the core near a distal end of the core, the coil terminating proximal of the distal end of the core and bonded to the core at the termination of the coil.--

Respectfully submitted,

Date: June 20, 2000

  
Todd P. Messal, Reg. No. 42,883  
Scimed Life Systems, Inc.  
One Scimed Place, M.S. A150  
Maple Grove, MN 55311-1566  
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By: Brenda House  
Name: Brenda House

## Field of the Invention

## Background of the Invention

Common gastrointestinal uses of guide wires include endoscopic procedures in which an endoscope may be inserted into the mouth and advanced through the esophagus to the bile duct, the cystic duct, or the pancreatic duct. A guide wire is then threaded through a lumen in the endoscope and into the bile duct, cystic duct, or pancreatic duct. Once the distal tip of the guide wire is located in a position desired to be treated, a catheter having a medical instrument on its distal end is advanced over the guide wire and



to the treatment area. The guide wire and the catheter may then be observed through the endoscope as treatment occurs.

Urological uses of guide wires include the placement of ureteral stents. Ureteral stenting is required when the normal flow of urine from the kidney into the bladder is  
5 compromised perhaps by tumor growth, stricture, or stones. Generally, the procedure involves the insertion of a ureteroscope through the urethra and into the bladder. A guide wire is then advanced through the ureteroscope and into a ureter. The wire is then forced through the compromised portion of the ureter. Once the guide wire is in place, a ureteral stent is advanced over the guide wire and into position in the ureter. The guide wire may  
10 then be removed and the stent will maintain the patency of the fluid path between the kidney and the bladder. The procedures described above are but a few of the known uses for guide wires.

Pushability, kink resistance, torqueability and bendability are closely related and important features of a guide wire. It is important that force applied at the proximal end  
15 of a guide wire is completely transferred to the distal end of the guide wire. Very stiff wires often provide good pushability (axial rigidity) but poor kink resistance. Kink resistance is measured by the ability of the guide wire to be forced into a relatively tight bend radius without permanently deforming the wire. A guidewire must exhibit good bendability. This characteristic is a balance between adequate flexibility to navigate a  
20 tortuous lumen and suitable rigidity to support tracking of another device such as a catheter. Torqueability is closely related to the torsional rigidity of the wire and is ultimately demonstrated by how well rotation imparted to the proximal end of the guide wire is translated to the distal end of the guide wire.

Conventional guide wires are made of carbon steel or stainless steel. More recently, guide wires made of super-elastic alloys have been used. A super-elastic or pseudoelastic metal guide wire was taught in U.S. Patent 4,925,445 to Sakamoto. In U.S. Patents 5,238,004 to Sahatjian and 5,230,348 to Ishibe the use of an elastic metal alloy was taught. Sahatjian '004 further teaches that elastic metals may be heat treated to form bends in the wire core and that centerless grinding may be used to create certain wire profiles.

Several different types of guide wires are well known in the art. One type of wire is characterized by a solid metal core surrounded by a metal coil. Typical metals for the core may include spring steels and stainless steels. The distal tip of the core may also be ground to a taper to provide added flexibility near the tip. Coils may be made of the same variety of metals used as core materials. The coil may be made of round wire or flat wire and may surround the entire length of the core or only a portion of the core. The coil usually is formed by helically wrapping the wire around a mandrel, removing the mandrel, and inserting the core into the coil. The pitch of the wire may be varied along the length of the coil to vary the stiffness of the coil.

High performance guide wires usually possess high kink resistance and excellent wire movement. The basic construction of a high performance wire is a Nitinol core surrounded by a lubricious coating. Unfortunately, Nitinol guide wires suffer from diminished pushability because the highly elastic Nitinol absorbs some of the force imparted to the proximal end of the wire. An improved high performance wire would provide better pushability to conventional super-elastic wires.

Traditional coil over core wires provide good axial stiffness and hence improved pushability. Traditional coil over core wires also provide dramatically improved kink resistance over stainless steel wires. However, because the coils tend to wind up on torque, coil over core wires tend to provide reduced torque transmission. Therefore, it would be advantageous to provide a coil over core wire with the torque transmission of a high performance wire.

### **Summary of the Invention**

The present invention overcomes the deficiencies of the prior art by providing a coil over core guide wire which has the kink resistance and wire movement of a super-elastic wire and the pushability and torque transmission of a coil over core wire. The guide wire has a nickel-titanium alloy core with a tapered distal tip. The core may be super-elastic or linear elastic.

A coil surrounds most of the core and may be bonded to the core. The coil may be stainless steel or nickel-titanium. The coil may be made of flat wire or round wire and may be made of a single strand or multifilar strands and may be a single coil or cross-wound coil.

The guide wire may further have a polymer tip which may be loaded with a radio-opaque material. The wire may also be coated with lubricious coatings. The polymer tip may also form a floppy tip without a safety ribbon.

### **Brief Description of the Drawings**

Figure 1 is a cross-section of a first embodiment of the guide wire.

Figure 2 is a cross-section of a second embodiment of the guide wire.

### Detailed Description of the Invention

The following detailed description should be read with reference to the drawings in which like elements in different drawing are numbered identically. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to  
5 limit the scope of the invention.

Examples of constructions, materials, dimensions, and manufacturing processes are provided for selected elements. All other elements employ that which is known to those skilled in the field of the invention. Those skilled in the art will recognize that many of the examples provided have suitable alternatives that may also be used.

10 Figure 1 shows a first embodiment of the guide wire 10. Core 20 may be 50-450 cm in length and 0.008-0.038 inches in diameter depending on the medical application. The distal portion 25 of core 20 may be tapered to provide flexibility to guide wire 10. Preferably the tapered distal portion 25 is formed by grinding 5-20 cm of core 20. The tapered distal portion 25 may be ground into a conical shape with a circular cross-section  
15 or stamped such that it has a rectangular cross-section.

Core 20 may be formed of a super-elastic material such as the alloys of nickel and titanium, commonly known as Nitinol. While Nitinol is the most common super-elastic material, any of a variety of other super-elastic materials may be used for core 20. Other alloys by chemical name include; CuAlNi, CuSn, CuZn, InTi, NiAl, FePt, MnCu, and  
20 FeMnSi. A detailed discussion of super-elastic alloys and their processing is presented in US Patent 4,925,445 to Sakamoto and is herein incorporated by reference.

In addition to super-elastic materials, linear-elastic materials may be used. Linear-elastic materials are describe in US Patent 5,238,004 to Sahatjian which is also

incorporated by reference. In general, linear-elastic materials are composed of the same alloys above. However, different material processing strategies are used to provide a wire which has many of the important characteristics of a super-elastic material without some of the difficulties related to machining, specifically grinding. As such, core 20 may  
5 preferably be formed of a linear-elastic alloy of nickel-titanium.

Surrounding core 20 is coil 30. Coil over core wires are well known in the art and are described in detail in US Patent 5,147,317 to Shank which is incorporated by reference. Coil 30 may be made of a variety of metallic materials including super-elastic or linear-elastic materials such as Nitinol, radio-opaque materials such as gold or  
10 tungsten, precipitation hardenable alloys such as the non-ferrous cobalt-based alloys MP35N or Elgiloy™ and the ferrous alloys such as K91 from Sanvic Corp. and PH455 from Carpenter, or more conventional stainless steel alloys such as 304. Preferably coil 30 may be 0.001-0.015 inches in diameter, and made of 304 stainless steel.

Coil 30 is wrapped around substantially the entire length of core 20. Preferably,  
15 coil 30 is not wrapped around the tapered distal portion 25 of core 20. Coil 30 may be formed of flat ribbon ranging in dimensions 0.001 - 0.003 inches in thickness by 0.005 to 0.015 inches in width . Coil 30 is wrapped in a helical fashion about core 20 by conventional winding techniques. The pitch of adjacent turns of coil 30 may be tightly wrapped so that each turn touches the succeeding turn or the pitch may be set such that  
20 coil 30 is wrapped about core 20 in an open fashion shown at 35. Preferably, the pitch coil 30 is such that the coils are tightly wrapped over most of the proximal portion of core 20 with the pitch of each turn changing such that coil 30 has an open wrap shown at 35

near the distal end of core 20. Varying the pitch of coil 30 allows guide wire 10 to have a more flexible distal segment.

Alternatively, coil 30 may be formed of cross-wound multifilar or multifilar single coil wire. Multifilar cross-wound coils are described in US Patent 4,932,419 to de

5 Toledo which is herein incorporated by reference. A cross-wound multifilar coil consists essentially of a first inner coil of multiple coil wires wound in a first helical direction and a second outer coil of multiple coil wires disposed about the first coil and wound in a second opposite helical direction. Coil over core wires tend to wind up and store energy when torqued rather than transmitting the torque. Multifilar coils provides less wind up and therefore lessen the potential for the distal tip of the wire to whip while the proximal end is being turned.

Bonding core 20 to coil 30 also improves the torque transmission of guide wire 10. Coil 30 may be bonded to core 20 along the length of core 20 or in discrete sections.

Bonding may be achieved in a variety of ways including using adhesives, brazing, 15 welding, crimping, and swaging. Welding may be done through any of the techniques known in the art including spot welding using laser or resistance welding or ball welding using laser or plasma welding. Soldering may be done through any of the techniques known in the art and must include the step of preparing the surface of the Nitinol core 20 by plating or etching. Preferably the coil 30 will be bonded to the core 20 by laser spot 20 welding thereby removing the need for preparing the surface of the core 20. Laser spot welding is also advantageous because it may be done through coatings.

An alternative method of bonding the coil 30 to the core 20 is to provide a stainless steel hypotube (not shown) with an inner diameter dimensioned to closely fit

about core 20. The stainless steel hypotube may then be crimped onto core 20 and the coil 30 wound about the hypotube. The hypotube then provides a surface which is much easier to bond to a stainless steel coil 30 using conventional methods. Metal foils or other materials may also be used as an intermediate which facilitates bonding between the coil 30 and the core 20.

Yet another bonding method utilizes the polymer jacket 40 of the distal tip. The polymer may be applied in a manner that allows the polymer to flow between the coil and core. The polymer will provide a high integrity bond which will help to prevent the polymer jacket from separating from the coil 30 and bond the coil to core 20. In addition to these improvements, the polymer coating will make a better transition from the core 20 to the distal portion 25. A tip bonded in this manner provides a further improvement by producing coloration differences between the coil wire and polymer. These differences act as stripes for the detection of guidewire advance in endoscopy application.

The distal portion 25 of core wire 20 may further include a polymer tip 40. Polymer tip 40 serves several functions. Polymer tip 40 improves the flexibility of the distal portion 25 of core wire 20. Choice of polymers for polymer tip 40 will vary the flexibility of the distal portion 25 of core wire 20. For example, polymers with a low durometer or hardness will make a very flexible or floppy tip. Conversely, polymers with a high durometer will make a wire tip which is stiffer.

Polymer tip 40 also provides a more atraumatic tip for guide wire 10. An atraumatic tip is better suited for passing through fragile body passages. Finally, polymer tip 40 may act as a binder for radio-opaque materials. Loading polymers with radio-

opaque materials is well known in the art for producing a bright image under fluoroscopy and thereby allowing the user of guide wire 10 a better understanding of where the distal portion 25 of guide wire 10 is located within a patient's body. Suitable medical grade radio-opaque materials include tungsten, platinum, and iridium.

5           Suitable polymeric materials for polymer tip 40 include urethanes, elastomeric nylons such as Pebax, silicones, and co-polymers. Polymer tip 40 may be a single polymer, multiple layers, or a blend of polymers.

Coating (not shown) may also be done to the wire proximal to polymer tip 40. Hydrophobic coatings such as fluoropolymers provide a dry lubricity which improves  
10   guide wire handling and device exchanges. A second lubricious polymer (not shown) may coat distal portion 25 of guide wire 10 or the entire wire 10. Lubricious coatings improve steerability and improve lesion crossing capability. Suitable lubricious polymers are well known in the art and may include hydrophilic polymers.

Guide wire 10 may further include a colored coating. Colored guide wires are  
15   described in detail in US Patent 5,739,779 to Rowland which is herein incorporated by reference. In general, colored coatings may improve the visibility of the guide wire when it is being used in an endoscopic procedure. Striping may also be done. Striping allows the physician to gauge wire movement and position. Striping may be achieved by spray coating different colors on the wire 10. Another way to stripe the wire 10 is to coat the  
20   wires of coil 30 prior to winding.

Figure 2 depicts a second embodiment of the high performance coil wire where like elements are similarly numbered. All design advantages, materials of construction, and methods of manufacture are similar to those described above unless explicitly



modified below. Guide wire 10 is comprised of a solid core 20 surrounded by a coil 30. The distal portion 25 of core 20 may be tapered as described above or preferably is not tapered. Similar to the embodiment of Figure 1, the distal portion 35 of coil 30 changes pitch to provide a softer less traumatic tip.

5           Guide wire 10 further includes a rounded tip 37. Tip 37 may be polymeric or a metal tip welded to the distal portion 35 of coil 30. Unlike common spring tipped guide wires, guide wire 10 does not have a safety ribbon connecting core 20 to tip 37. Instead guide wire 10 may include a polymer 40 which may be flowed into the space between coils 35 and the space between the distal portion 25 and tip 37. Suitable polymers are  
10       described above where choice of polymer may control the flexibility of the tip. Polymer 40 may also be loaded with radio-opaque materials. Finally, guide wire 10 may be coated as described above and may also include various colors or stripes. The distal portion of guide wire 10 is thereby provided with a very floppy tip which uses polymer 40 as a safety ribbon instead of a metallic safety ribbon. Guide wire 10 is provided with the  
15       advantage that core 20 does not need to be ground.

While the specification describes the preferred designs, materials, methods of manufacture and methods of use, those skilled in the art will appreciate the scope and spirit of the invention with reference to the following claims.

We claim:

1. A guide wire comprising:  
  
an elongate core composed of a nickel-titanium alloy; and  
  
a coil composed of a second material and surrounding a substantial portion  
  
of the core.
2. The guide wire of claim 1 wherein the nickel-titanium alloy comprises a super-elastic metal.
3. The guide wire of claim 1 wherein the nickel-titanium alloy comprises a linear-elastic metal.
4. The guide wire of claim 1 wherein the second material comprises a nickel-titanium alloy.
5. The guide wire of claim 4 wherein the nickel-titanium alloy comprises a super-elastic metal.
6. The guide wire of claim 4 wherein the nickel-titanium alloy comprises a linear-elastic metal.
7. The guide wire of claim 1 wherein the second material comprises stainless steel.
8. The guide wire of claim 1 wherein the second material comprises a precipitation hardenable alloy.
9. The guide wire of claim 1 further comprising:  
  
a polymer tip surrounding a distal portion of the core wire.
10. The guide wire of claim 9 wherein the polymer tip comprises a radio-opaque filler whereby a distal tip of the guide wire may be more readily visible under fluoroscopy.

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11. The guide wire of claim 1 wherein the coil comprises a single strand of wire.
  12. The guide wire of claim 1 wherein the coil comprises a multi-filar strand.
  13. The guide wire of claim 11 wherein the wire further comprises a rectangular cross-section.
  14. The guide wire of claim 11 wherein the wire further comprises a circular cross-section.
  15. The guide wire of claim 1 wherein the coil further comprises a pitch which varies along the length of the coil.
  16. The guide wire of claim 15 wherein the pitch of the coil varies such that a distal end of the coil is more flexible than a proximal end of the coil.
  17. The guide wire of claim 1 further comprising:
    - a hypotube, joined to the core and bonded to the coil.
  18. The guide wire of claim 1 wherein a bond is formed between the coil and the core.
  19. The guide wire of claim 18 wherein the bond comprises a weld bond.
  20. The guide wire of claim 18 wherein the bond comprises an adhesive bond.
  21. A floppy-tipped guide wire comprising:
    - a core;
    - a coil surrounding at least a distal portion of the core, a distal end of the coil extending distal of the distal portion of the core,
    - a tip bonded to the distal end of the coil; and
    - a polymeric safety ribbon bonding the distal portion of the core to the tip.

## **Abstract**

A high performance coil over-core guide wire. The guide wire incorporates a nickel-titanium core with a stainless steel coil to provide a wire with improved kink resistance and good pushability.

5

**CERTIFICATE UNDER 37 C.F.R. § 1.10:**

"Express Mail" mailing label number: EM330477640US

Date of Deposit: May 14, 1998

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By: Debra H. Rheume  
Name: Debra H. Rheume

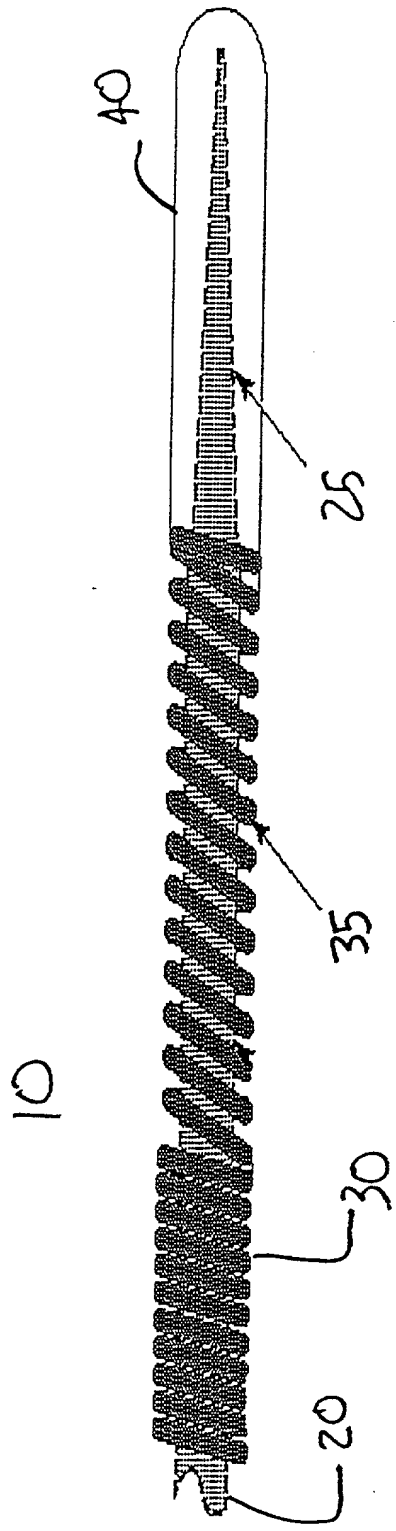


FIG. 1

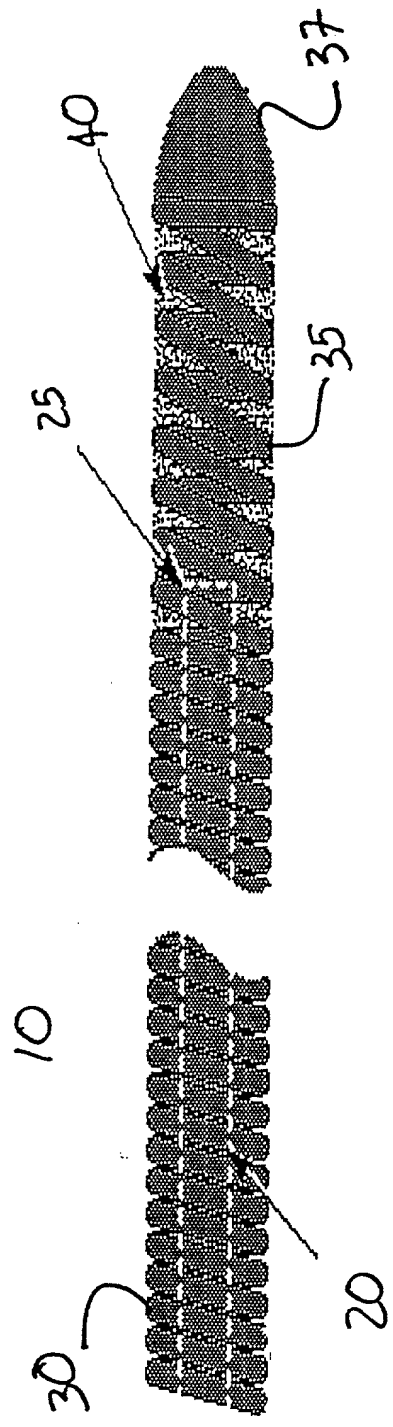


FIG. 2

SCIMED Life Systems, Inc.

COMBINED DECLARATION AND POWER OF ATTORNEY  
for UNITED STATES PATENT APPLICATION

As a named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or original, first and joint inventor (if plural names are listed below) of the subject matter claimed and disclosed in the patent application entitled: **HIGH PERFORMANCE COIL WIRE**, which is attached hereto or (if not attached) was filed on **May 14, 1998**, as a U.S. (or PCT) Patent Application Number **09/078,946** and was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which may be material to patentability under 37 CFR § 1.56 (see page 3 attached hereto).

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d)/365 of any foreign patent application(s) or inventor's certificate(s) listed below.

FOREIGN PATENT APPLICATION OR CERTIFICATE NUMBER	DATE OF FILING (day, month, year)	COUNTRY
(none)		

I hereby claim priority benefits under 35 U.S.C. § 119(e) of any U.S. provisional patent application(s) listed below.

U.S. PROVISIONAL PATENT APPLICATION NUMBER	DATE OF FILING (day, month, year)	DOCKET NUMBER (if applicable)
(none)		

I hereby claim the benefit under 35 U.S.C. § 120 of any United States Patent Application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by 35 U.S.C. § 112 first paragraph, I acknowledge the duty to disclose information which may be material to patentability under 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. PATENT APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (pending, patented, abandoned)
(none)		

## POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

**Robert E. Atkinson, Reg. No. 36,433;**  
**Luke Dohmen, Reg. No. 36,783;**  
**Peter J. Gafner, Reg. No. 36,517;**  
**Todd P. Messal, Reg. No. P-42,883**

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct SCIMED Life Systems, Inc. to the contrary.

Please direct all correspondence in this case to SCIMED Life Systems, Inc. at the below address:

One SCIMED Place  
Mail Stop A150  
Maple Grove, Minnesota 55311-1566  
Attn: Todd P. Messal  
(612) 494-2880

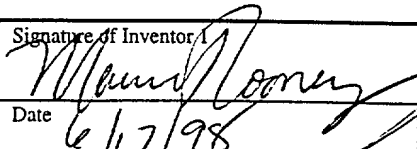
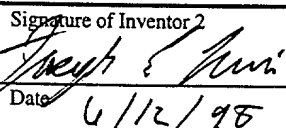
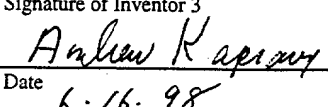
I hereby believe that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

### NAMED INVENTOR(S)

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<b>Signature of Inventor 1</b> 	<b>Signature of Inventor 2</b> 	<b>Signature of Inventor 3</b> 
<b>Date</b> 6/17/98	<b>Date</b> 6/12/98	<b>Date</b> 6.16.98

For Additional Inventors:

☒ Indicate here and attach sheet with same information, including date and signature.

**§ 1.56 Duty to disclose information material to patentability.**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor.



# ADDITIONAL NAMED INVENTOR(S)

4

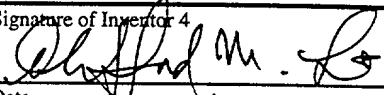
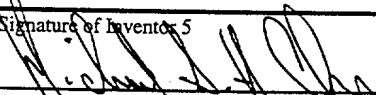
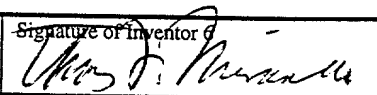
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5

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Signature of Inventor 4 	Signature of Inventor 5 	Signature of Inventor 6 
Date 6/12/98	Date June 12 1998	Date 6/19/98